

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

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DEVRA HANEY-WILLIAMS,

Plaintiff(s),

v.

GLAXOSMITHKLINE LLC, et al,

Defendant(s).

Case No. 2:17-CV-2900 JCM (EJY)

ORDER

Presently before the court is plaintiff Devra Haney-Williams (“plaintiff”)’s motion to strike defendant Sam’s West Inc. d/b/a Sam’s Pharmacy #10-4974 (“defendant”)’s expert Neal L. Benowitz, M.D. (“Dr. Benowitz”). (ECF No. 138). Defendant responded. (ECF No. 152). Plaintiff replied. (ECF No. 161).

Also before the court is defendant’s motion for summary judgment. (ECF No. 136). Plaintiff responded. (ECF No. 156). Defendant replied. (ECF No. 163).

Also before the court is plaintiff’s motion for summary judgment. (ECF No. 139). Defendant responded. (ECF No. 151). Plaintiff replied. (ECF No. 162).

I. INTRODUCTION

This matter arises from plaintiff’s adverse reaction to the drug lamotrigine. Plaintiff was prescribed lamotrigine to treat seizure disorders. She was given two prescriptions: one for 25mg pills and one for 100mg pills. Her doctor instructed her to take one 25mg pill per day for the first week, two 25mg pills per day for the second week, three per day for the third week, and so on. Observing this dose escalation would result in a 100mg dose per day on the fourth week. The 100mg pill prescription was provided to reduce the number of pills plaintiff would have to take when she reached higher doses. However, only the 100mg-pill prescription was filled. Plaintiff then proceeded to take one 100mg pill on the first day, and three 100mg pills on the second day—twelve times the dosage prescribed by her doctor.

1 Lamotrigine, also known by its brand name Lamictal, is accompanied by a FDA-
 2 approved black box warning; black box warnings are the most serious type of warning that the
 3 FDA gives a medication. They are meant to warn of serious or life-threatening risks associated
 4 with the drug. The relevant part of lamotrigine’s black box warning warns of rash development.

5 Shortly after starting the medication, plaintiff developed a rash. The rash evolved into
 6 toxic epidermal necrolysis, also referred to as Stevens-Johnson syndrome (herein, “SJS”), a
 7 condition that caused blistering and skin loss over 80% of her body. The operative complaint
 8 alleges SJS resulted in injuries to the majority of plaintiff’s body, including internal organs.
 9 Plaintiff also alleges the condition caused permanent blindness and neurological injuries.
 10 Plaintiff brought a negligence action against various involved parties to recover for her injury.
 11 The only remaining claim is a negligence claim against defendant.

12 The parties do not dispute that lamotrigine caused SJS and consequently plaintiff’s
 13 associated injuries. The dispositive dispute herein is whether the *extra* dosage dispensed to
 14 plaintiff by defendant caused SJS.

14 **II. LEGAL STANDARD**

15 *a. Expert witness*

16 Federal Rule of Evidence 702 provides that a witness qualified as an expert may testify if
 17 “(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to
 18 understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient
 19 facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the
 20 expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid.
 702.

21 Federal Rule of Evidence 702 controls the court’s determination whether to strike a
 22 proposed expert witness. “*Daubert*’s general holding—setting forth the trial judge’s general
 23 ‘gatekeeping’ obligation—applies not only to testimony based on ‘scientific’ knowledge, but
 24 also to testimony based on ‘technical’ and ‘other specialized’ knowledge.” *Kumho Tire Co. v.*
 25 *Carmichael*, 526 U.S. 137, 141 (1999); *see Daubert v. Merrel Dow Pharm., Inc.*, 509 U.S. 579,
 26 597 (1993). This “gatekeeping obligation” requires “that all admitted expert testimony is both
 27 relevant and reliable.” *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017).
 28 Expert testimony must be relevant and reliable, and it must “relate to scientific, technical, or

1 other specialized knowledge, which does not include unsupported speculation and subjective
2 beliefs.” *Guidroz–Brault v. Missouri Pac. R.R. Co.*, 254 F.3d 825, 829 (9th Cir. 2001).

3 Exclusion of expert testimony is proper only when such testimony is irrelevant or
4 unreliable because “[v]igorous cross-examination, presentation of contrary evidence, and careful
5 instruction on the burden of proof are the traditional and appropriate means of attacking shaky
6 but admissible evidence.” *Daubert*, 509 U.S. at 596 (citing *Rock v. Arkansas*, 483 U.S. 44, 61
(1987)).

7 *b. Summary judgment*

8 The Federal Rules of Civil Procedure allow summary judgment when the pleadings,
9 depositions, answers to interrogatories, and admissions on file, together with the affidavits, if
10 any, show that “there is no genuine dispute as to any material fact and the movant is entitled to a
11 judgment as a matter of law.” Fed. R. Civ. P. 56(a). A principal purpose of summary judgment
12 is “to isolate and dispose of factually unsupported claims.” *Celotex Corp. v. Catrett*, 477 U.S.
13 317, 323–24 (1986).

14 For purposes of summary judgment, disputed factual issues should be construed in favor
15 of the nonmoving party. *Lujan v. Nat’l Wildlife Fed.*, 497 U.S. 871, 888 (1990). However, to
16 withstand summary judgment, the nonmoving party must “set forth specific facts showing that
17 there is a genuine issue for trial.” *Id.*

18 When the nonmoving party bears the burden of proving the claim or defense, the moving
19 party can meet its burden in two ways: (1) by presenting evidence to negate an essential element
20 of the nonmoving party’s case; or (2) by demonstrating that the nonmoving party failed to make
21 a showing sufficient to establish an element essential to that party’s case on which that party will
22 bear the burden of proof at trial. *See Celotex Corp.*, 477 U.S. at 323–24. If the moving party
23 fails to meet its initial burden, summary judgment must be denied, and the court need not
24 consider the nonmoving party’s evidence. *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 159–
25 60 (1970).

26 If the moving party satisfies its initial burden, the burden then shifts to the opposing party
27 to establish that a genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith*
28 *Radio Corp.*, 475 U.S. 574, 586 (1986). The opposing party need not establish a dispute of
material fact conclusively in its favor. *See T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass’n*,

1 809 F.2d 626, 631 (9th Cir. 1987). It is sufficient that “the claimed factual dispute be shown to
 2 require a jury or judge to resolve the parties’ differing versions of the truth at trial.” *Id.*

3 In other words, the nonmoving party cannot avoid summary judgment by relying solely
 4 on conclusory allegations that are unsupported by factual data. *See Taylor v. List*, 880 F.2d
 5 1040, 1045 (9th Cir. 1989). Instead, the opposition must go beyond the assertions and
 6 allegations of the pleadings and set forth specific facts by producing competent evidence that
 7 shows a genuine issue for trial. *See Celotex*, 477 U.S. at 324.

8 At summary judgment, a court’s function is not to weigh the evidence and determine the
 9 truth, but to determine whether a genuine dispute exists for trial. *See Anderson v. Liberty Lobby, Inc.*,
 10 477 U.S. 242, 249 (1986). The evidence of the nonmovant is “to be believed, and all
 11 justifiable inferences are to be drawn in his favor.” *Id.* at 255. But if the evidence of the
 12 nonmoving party is merely colorable or is not significantly probative, summary judgment may be
 13 granted. *See id.* at 249–50.

14 The Ninth Circuit has held that information contained in an inadmissible form may still
 15 be considered for summary judgment if the information itself would be admissible at trial.
 16 *Fraser v. Goodale*, 342 F.3d 1032, 1036 (9th Cir. 2003) (citing *Block v. City of Los Angeles*, 253
 17 F.3d 410, 418–19 (9th Cir. 2001) (“To survive summary judgment, a party does not necessarily
 18 have to produce evidence in a form that would be admissible at trial, as long as the party satisfies
 19 the requirements of Federal Rules of Civil Procedure 56.”)).

18 **III. DISCUSSION**

19 *a. Plaintiff’s motion to strike defendant’s expert Dr. Neal Benowitz, M.D.*

20 Plaintiff takes issue with Dr. Benowitz’s second opinion (the “opinion”), which plaintiff
 21 succinctly summarizes as:

22 [T]he higher than recommended initial dose of Lamotrigine
 23 contributed to the development of SJS in plaintiff because the
 24 development of SJS from higher than recommended initial doses
 25 have [sic] been “suggested not proven” and plaintiff “may well
 26 have developed SJS had she received” the recommended initial
 27 dose.

28 (ECF No. 138 (citing (ECF No. 138-1))). Plaintiff also takes issue with Dr. Benowitz’s assertion
 that the rarity of SJS suggests another disease mechanism is occurring. (*Id.* citing (ECF No. 138-
 1)). Finally, plaintiff contends Dr. Benowitz’s testimony will not assist the trier of fact to

1 understand the evidence or determine a fact in issue. (*Id.*). Underlying plaintiffs’ arguments is
 2 the assertion that the opinion is not based on sufficient facts or data and is not the product of
 3 reliable principles. (*Id.*).

4 In forming the opinion, Dr. Benowitz relied on a 1998 study published by the
 5 manufacturer of lamotrigine (the “1998 study”), records from various entities,¹ plaintiff’s
 6 answers to interrogatories, as well as depositions of plaintiff, her treating physician, and the
 7 pharmacist who dispensed the lamotrigine to plaintiff. (ECF No. 138-1). In addition, Dr.
 8 Benowitz, *inter alia*, served for years as chief of clinical pharmacology and medical toxicology
 9 and University of California San Francisco and at the time of forming the opinion, served as a
 10 chair for the pharmacy and therapeutics committee at San Francisco General Hospital and
 11 focused his clinical practice on cardiovascular medicine, medical toxicology, and clinical
 12 pharmacology. (ECF No. 152). He further relied on his experience and specialized knowledge
 to help form an opinion. (*Id.*).

13 Plaintiff cites her own expert to attack the opinion and Dr. Benowitz’s basis for the
 14 opinion. (ECF No. 138). The court will not engage in a credibility analysis of experts. *See*
 15 *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (finding credibility determinations to
 16 be a function of a jury). Indeed, the appropriate place to attack an expert’s factual basis is in
 17 front of a trier of fact. *Daubert*, 509 U.S. at 596. Plaintiff instead asks this court to take her
 18 expert’s opinion as fact, strike defendant’s expert as a result thereof, and grant summary
 judgment pursuant these findings. (ECF Nos. 138, 139).

19 The court finds that the opinion is based on a sufficient factual basis to be admissible.
 20 Dr. Benowitz’s experience is specialized in the medical toxicology and pharmacology fields, he
 21 relied on various records specific to this case as well as outside scientific information, and he
 22 drew reasonable conclusions therefrom. (ECF No. 138-1); *see* Fed. R. Evid. 702. Though
 23 plaintiff takes issue with Dr. Benowitz’s reliance on one 1998 study, without more evidence to
 24 the contrary, this reliance is insufficient to strike the opinion or expert. *See Boyd v. City of San*
 25 *Francisco*, 576 F.3d 938, 946 (9th Cir. 2009) (affirming the district court’s admission of expert
 26 testimony because the testimony “pass[ed] muster”).

27 ...

28 ¹ “I have reviewed medical records from Mountain View Hospital, University Medical Center,
 Sam’s pharmacy, Raxo Drugs...”. (ECF No. 138-1).

1 Thus, plaintiff's motion to strike is DENIED.

2 *b. Defendant's motion for summary judgment*

3 Plaintiff asserts only negligence against defendant. A plaintiff must establish four
4 elements to succeed on a negligence claim: (1) a duty of care, (2) a breach of that duty,
5 (3) causation, and (4) damages. *Turner v. Mandalay Sport Entm't*, 180 P.3d 1172, 1175 (Nev.
6 2008). Defendant's motion for summary judgment relies almost entirely on plaintiff's inability
7 to show causation. (ECF No. 136). The court may grant summary judgment if plaintiff cannot
8 establish one or more of the elements of negligence against defendant. *See Celotex Corp.*, 477
9 U.S. at 322. Thus, defendant argues, defendant is entitled to summary judgment in its favor
because plaintiff cannot prove the causation element of negligence. *See id.*; (ECF No. 138).

10 Plaintiff alleges defendant was negligent because (1) defendant did not provide a starter
11 kit or medication guide as recommended by the drug manufacturer and (2) dispensed 100mg
12 tablets rather than 25mg tablets of lamotrigine to plaintiff. (ECF No. 30). Thus, plaintiff must
13 prove by a preponderance of the evidence that the additional dosage caused her injuries. Stated
14 another way, plaintiff must show that she would not have developed SJS if she had taken the
15 medication as prescribed. It follows that defendant must show there is not a genuine issue of
16 material fact regarding the causation element to warrant summary judgment.

17 In her opposition to defendant's motion, plaintiff contends that "at the very least, she has
18 presented a question of fact as to causation." (ECF No. 156). In support, she points to expert
19 testimony on medical causation as well as the FDA-approved black box warning associated with
lamotrigine. (*Id.*).

20 *i. Expert testimony on medical causation*

21 Whether plaintiff's proposed experts have the qualifications to render medical opinions is
22 a disputed issue. For the purposes of summary judgment, however, the court considers the
23 evidence in favor of the nonmoving party and thus considers plaintiff's experts' opinions on
24 medical causation admissible as such, subject to other rules of evidence at the summary
judgment stage.

25 "[M]edical expert testimony on the issue of causation must be stated to a reasonable
26 degree of medical probability." *Morsicato v. Sav-On Drug Stores, Inc.*, 111 P.3d 1112, 1116
27 (Nev. 2005). In other words, a medical expert opinion must state causation with a degree of
28 certainty that the alleged cause is more than 50% likely to have actually caused the injury, or the

1 testimony may be stricken. *See id.* at 1114. If a medical expert cannot make a medical judgment
 2 with the requisite degree of medical probability, then there would be no expert testimony on the
 3 record to assist a trier of fact to make factual determination. *See id.* at 1116.

4 Before the court presently are reports and depositions from plaintiff's proposed experts,
 5 Michael Iglinski, RPh² ("Iglinski"), and Dr. Mark Decerbo, PharmD, BCPS, BCNSP³ ("Dr.
 6 Decerbo").

7 1. Iglinski

8 Iglinski's deposition testimony opines that a higher dosage of lamotrigine is more likely
 9 to cause SJS than the recommended 25mg. (ECF No. 156-13). However, when asked if he
 10 believed "to a reasonable degree of certainty that had [plaintiff] started with her 25 milligrams
 11 per day...that she would not have suffered [SJS]," Iglinski answered in the negative. (*Id.*).
 12 Without the requisite level of certainty, Iglinski's opinion on medical causation does not prove
 the higher-than-prescribed dosage caused plaintiff's injuries. *See Morsicato*, 111 P.3d at 1116.

13 2. Dr. Decerbo

14 When asked if plaintiff—had she taken the 25mg dosage lamotrigine as prescribed—
 15 would be "more likely than not" to avoid developing SJS versus taking the higher dosage
 16 dispensed by defendant, Dr. Decerbo agreed that would be too speculative to conclude. (ECF
 17 No. 156-17). Plaintiff argues this is a mischaracterization of his testimony contending that Dr.
 18 Decerbo's testimony actually asserts plaintiff, had she taken the prescribed 25mg dosage, "would
 19 be less likely to suffer an adverse reaction but that to say she would not have suffered an adverse
 20 reaction with the correct initial dose would be speculation." (ECF No. 156). The court
 disagrees.

21 With her opposition, plaintiff submits a declaration by Dr. Decerbo executed after his
 22 deposition taken under oath. (ECF No. 156-16). The declaration is in direct contradiction to his
 23 deposition testimony, now asserting his opinion is that "more likely than not, the inappropriately
 24 high initial dose dispensed to [plaintiff] caused the life-threatening symptoms she suffered."
 25 (*See id.*).

26
 27 ² RPh indicates Iglinski is a licensed pharmacist.

28 ³ PharmD indicates Dr. Decerbo is a doctor of pharmacy, BCPS indicates he is a board certified
 pharmacotherapy specialist, and BCNSP indicates he is a board certified nutrition support pharmacist.

1 This self-serving declaration is insufficient to create an issue of fact sufficient to avoid
 2 summary judgment under the sham affidavit rule. *See Kennedy v. Allied Mut. Ins. Co.*, 952 F.2d
 3 262 266 (9th Cir. 1991) (“The general rule in the Ninth Circuit is that a party cannot create an
 4 issue of fact by an affidavit contradicting his prior deposition testimony.”). While plaintiff is not
 5 precluded from explaining or clarifying prior deposition testimony, the declaration clearly and
 6 unambiguously contradicts Dr. Decerbo’s opinion on the medical causation at issue here and is
 7 thus a “sham.” *See Van Asdale v. Int’l Game Tech.*, 577 F.3d 989, 998–99 (9th Cir. 2009) (citing
Messick v. Horizon Indus., 62 F.3d 1227, 1231 (9th Cir. 1995)).

8 ii. FDA-approved black box warning

9 Plaintiff contends that the black box warning associated with lamotrigine is evidence that
 10 a higher-than-25mg dose is evidence of causation. (ECF No. 156). In support of this argument,
 11 plaintiff points specifically to the language that says “exceeding the recommended dose of
 12 Lamotrigine, or [] exceeding the recommended dose escalation for Lamotrigine” may increase
 13 the risk of rash. (*Id.*). This warning is qualified, however, in that it is a “suggestion[], yet to be
 14 proven” and relates only to rashes in general—most of which are benign—rather than SJS. (*See*
 15 *id.*). Indeed, the only portion of the warning that relates to severity of rash states that “[o]ther
 16 than age, there are as yet no factors identified that are known to predict the risk of occurrence or
 17 the severity of rash caused by Lamotrigine.” (*Id.*).

18 Even if FDA-approved warnings may be considered by a jury for the issue of causation
 19 as plaintiff contends, nothing in the black box warning in this matter warning creates a genuine
 20 issue of material fact as to causation. (*See* ECF No. 156 (citing *R.T. v. Knobloch*, 111 N.E. 3d
 21 588, 601 (Ohio Ct. App. 2018)). The black box warning regarding rashes is “merely colorable”
 22 and “not significantly probative.” *See Anderson*, 477 U.S. at 249–50 (1986).

23 The court finds that plaintiff has not presented sufficient evidence to show a genuine
 24 issue of material fact regarding causation. Plaintiff would be unable to prove by a preponderance
 25 of the evidence an essential element to her claim. Thus, summary judgment is appropriate. *See*
Celotex Corp., 477 U.S. at 322.

26 **IV. CONCLUSION**

27 Accordingly,

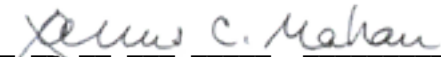
28 IT IS HEREBY ORDERED, ADJUDGED, and DECREED that plaintiff’s motion to
 strike (ECF No. 138) is DENIED.

1 IT IS FURTHER ORDERED that defendant's motion for summary judgment (ECF No.
2 136) is GRANTED.

3 IT IS FURTHER ORDERED that plaintiff's motion for summary judgment (ECF No.
4 139) is DENIED as moot.

5 The clerk is instructed to enter judgment in favor of defendant and close this case.

6 DATED March 20, 2023.

7 
8 UNITED STATES DISTRICT JUDGE